UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JULIANNE NUNNELLY and MATTHEW SHANKS Plaintiffs, v. REGENERON PHARMACEUTICALS, INC., Defendant.	No. 20-cv-11401-PBS Leave to file granted on September 17, 2024

GOVERNMENT OPPOSITION TO
REGENERON'S MOTION TO DISMISS

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INTRODUCTION

The United States' and the States' respective Complaints (ECF Nos. 58, 128; the "Complaint" and the "Consolidated Complaint") allege that Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") paid hundreds of millions of dollars in price concessions to its customers for its blockbuster drug, Eylea. Regeneron knowingly failed to incorporate these price concessions in its Average Sales Price ("ASP") reports to the Centers for Medicare and Medicaid Services ("CMS"), which inflated Medicare's and Medicaid's payments for the drug and unjustly enriched the company. Yet, in its Memorandum (ECF No. 146, "Mem.") Regeneron repeatedly misstates and mischaracterizes the Complaint's factual allegations and ignores the relevant law.

The Complaint alleges with particularity that Regeneron paid distributors to subsidize physician customers' credit card purchases of Eylea and that these payments (herein "credit card subsidies") were not for distribution services. The Complaint further alleges that Regeneron knew Medicare regulations required it to report these credit card subsidies as price concessions in Eylea ASP reports. Nevertheless, Regeneron knowingly submitted false ASP reports that failed to account for these price concessions and caused the submission of false claims to Medicare for Eylea at inflated rates, in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, as well as to the intervening States' Medicaid programs, in violation of state laws, as detailed in the States' Consolidated Complaint.

Instead of taking the Complaint's allegations as true, as required at this stage, Regeneron attempts to substitute its own facts. Regeneron falsely asserts that distributors offered a "single cash-or-credit price" for Eylea and that its credit card subsidies were for distribution services—which the Complaint alleges Regeneron knew was not true. *See, e.g.*, Mem. at 1, 3-4, 13-15, 17,

19-22. In reality, Regeneron knew that without its subsidies, Eylea distributors would charge physician customers a higher price if they paid for Eylea with a credit card. *See, e.g.*, Compl. ¶ 59. Regeneron also knew its physician customers wanted to reap credit card rewards on millions of dollars of drug purchases. Regeneron thus paid for its customers' credit card surcharges through its subsidy payments, effectively lowering the price of Eylea for those customers who used a credit card. Accordingly, Regeneron's subsidy payments were price concessions that should have been incorporated into its ASP reports. Regeneron's attempt to recharacterize its subsidy payments as a distribution "service" is contrary to the facts alleged in the Complaint, and impermissible at the motion to dismiss stage. *See Foley v. Wells Fargo Bank, N.A.*, 772 F.3d 63, 75 (1st Cir. 2014) (court must accept plaintiff's well-pleaded allegations as true).

On the law, Regeneron ignores the plain language of the applicable regulation on the reporting of price concessions in ASP. That regulation, 42 C.F.R. § 414.804(a)(2)(i), requires manufacturers to report *all* price concessions, not only the exemplars in subsection (a)(2)(i)(A)-(E). Regeneron's argument that manufacturers are not required to report price concessions beyond the categories mentioned in subsections (A)-(E) of the regulation conflicts with the applicable statute and regulation's express language and is simply wrong. And Regeneron's own behavior undercuts this argument: Regeneron undertook significant efforts to disguise its payments as Bona Fide Service Fees ("BFSFs") to avoid reporting the payments as price concessions in the first place. Compl. ¶ 93.

Despite Regeneron's claims to the contrary, the Complaint alleges Regeneron acted knowingly under the FCA. Regeneron had two incompatible aims: (1) to provide price concessions to Eylea customers via its credit card subsidies, while (2) achieving its competitive

strategy of maintaining a steady, inflated ASP, both of which it knew would entice physicians' purchases of Eylea. The only way to realize both objectives was to submit fraudulently inflated Eylea ASP reports that failed to deduct the credit card subsidies. Regeneron knew the law, was aware of applicable regulations and guidance, failed to follow its policies concerning price concessions and BFSFs, and was specifically told by its "third-party experts," Mem. at 12, that the credit card subsidies were not for a type of service that could be a BFSF. Compl. ¶ 98. The Complaint thus alleges that Regeneron acted with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of its Eylea ASP reports. *See* 31 U.S.C. § 3729(b)(1). Regeneron's attempt to backdoor a scienter defense by asserting that its "interpretation was and is at the very least a reasonable one," Mem. at 27-28, fails. The Supreme Court has expressly rejected the relevance of *post hoc* "objective" interpretations to an FCA defendant's scienter. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 757 (2023) ("[I]t does not matter whether [there is] some other, objectively reasonable interpretation of" a regulation if a complaint alleges the defendant acted with scienter under the FCA). At best, Regeneron has raised a factual dispute as to its actual contemporaneous interpretation, which cannot be resolved by the Court on a motion to dismiss.

The Complaint pleads—and specifically identifies—false claims under the FCA, as does the Consolidated Complaint under state statutes. This Court has held that, where a manufacturer manipulates price reports to inflate the amount the government pays, the manufacturer causes the submission of false claims. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007) (rejecting defense argument, under state FCA analog, that "claims submitted to the government by providers do not contain any false pricing information because the allegedly inflated [price reports] for defendants' drugs are not included on the claim

form submitted to [the government program]."); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 19 (D. Mass. 2007) (rejecting same argument under the FCA, citing *id.* at 172-175). The same is true here. Regeneron's conduct was designed to and did inflate Eylea payment rates by Medicare and the intervening States' Medicaid programs. Regeneron therefore knowingly submitted false statements material to false claims and caused the submission of false claims at those inflated rates.

Lastly, Regeneron's claim that enforcement of this case would put "millions of Americans in legal jeopardy" or that Regeneron is accused of doing what "millions of businesses" do is a misguided attempt to conjure a "parade of horribles" that is, to borrow Regeneron's phrase, "divorced from reality." Mem. at 1. The allegations in this case have nothing to do with consumer conduct and are specific to Regeneron's obligation to accurately report prices for drugs paid for from the public fisc. For average Americans and businesses, the question of who pays credit card transaction fees and who receives credit card rewards is simply a contractual matter. The allegations in this case—that Regeneron paid subsidies on behalf of Eylea customers and knowingly failed to incorporate those price concessions into its ASP reports—are specific to Medicare and Medicaid payments for physician-administered drugs.

For these reasons, the Court should deny Regeneron's Motion.

LEGAL BACKGROUND

I. MEDICARE PART B AND ASP

Medicare Part B pays for Eylea and other physician-administered drugs at a statutorily determined rate based on the manufacturer reported ASP—typically 106% of ASP, less the applicable patient coinsurance. *See* 42 U.S.C. § 1395w–3a(b). A drug's ASP is based on the average price for sales of that drug in the United States, minus price concessions. Compl. ¶ 5.

Drug manufacturers must report the ASP of each of their Part B drugs to the Centers for Medicare and Medicaid Services ("CMS") on a quarterly basis. 42 C.F.R. § 414.804(a)(5). The Medicare program uses those reports to set Medicare payment rates. *See* Compl. ¶¶ 25, 30.

The ASP payment methodology was implemented as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 177 Stat 2066. Under the MMA, the ASP "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates"—referred to herein as the "enumerated categories." 42 U.S.C. § 1395w–3a(c)(3). The statute continues: "For years after 2004, the Secretary may include in such price other price concessions . . . that would result in a reduction of the cost to the purchaser." *Id.*

In April 2004, CMS issued an "interim final rule" requiring manufacturers to include the enumerated categories of price concessions in ASP. 69 Fed. Reg. 17,935, 17,938 (Apr. 6, 2004); 42 C.F.R. § 414.804(a)(2) (2004). At that time there was no statutory or regulatory mention of BFSFs. In August and December 2006, CMS proposed and implemented the current regulations that require manufacturers to report *all* price concessions in ASP. 71 Fed. Reg. 48,982, 49,082 (Aug. 22, 2006); 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006); 42 C.F.R. § 414.804(a)(2)(i) & (ii). CMS's final regulation states: "In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions." 42 C.F.R. § 414.804(a)(2)(i). Section 414.804(a)(2)(i) continues: "Price concessions *include*" the enumerated categories of price concessions. 42 C.F.R. § 414.804(a)(2)(i)(A)-(E) (emphasis added). As part of that same rulemaking, the regulations established that BFSFs are not price concessions. 42 C.F.R. § 414.804(a)(2)(ii) ("For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions."). BFSFs are defined as:

> fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 C.F.R. § 414.802. For a payment to qualify as a BFSF and be excluded from ASP, it must meet each of these elements. As CMS explained in guidance accompanying its 2006 final rule, the purpose of the BFSF provision is to distinguish price concessions from service fees:

> We believe that if a fee satisfies the definition of bona fide services fees it can be excluded from the calculation of the ASP. . . . This is because, taken together, this [sic] four elements describe those situations in which we believe a fee paid is compensation for services *rather than a price concession for drugs.*

71 Fed. Reg. 69,624, 69,668 (Dec. 1, 2006) (emphasis added). Accordingly, the Secretary exercised its statutory authority to require the inclusion of "other price concessions" in ASP reporting—to include all price concessions—while excluding any payments that constitute BFSFs.

II. THE FALSE CLAIMS ACT

"Congress wrote [the FCA] expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook County., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (internal quotation omitted). The FCA imposes liability on any person (1) who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or (2) who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). The language of the FCA "indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943); *see also United States ex rel.*

Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 390 (1st Cir. 2011); *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, No. 15-13065-PBS, 2018 WL 4539684, at *4 (D. Mass. Sept. 21, 2018).

The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 178 (2016). Conduct that improperly inflates government payment amounts is inherently material. *See United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009) ("Reporting false [Average Wholesale Prices] had a natural tendency to influence the Government's actions, by inflating the amount of the Government's payment.") (quotations and alteration marks omitted)); *Mass. v. Mylan Lab'ys*, 608 F. Supp. 2d 127, 153 (D. Mass. 2008) ("Reporting false [wholesale acquisition costs] had a natural tendency to influence the [state's] actions, by inflating the amounts used to compute [estimated acquisition cost], and thus potentially the amount of the [state's] payment."); *United States ex rel. Hueseman v. Prof'l Compounding Ctrs. of Am., Inc.*, 664 F. Supp. 3d 722, 748 (W.D. Tex. 2023) (holding "as a practical matter, [a price report] is inherently material under the language of the statute because, as part of the pricing calculation, it has 'a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'") (quoting 31 U.S.C. § 3729(b)(4)).

Under the FCA, to prove a defendant acted "knowingly," the government need not prove specific intent to defraud, 31 U.S.C. § 3729(b)(1)(B), but rather must establish that the person acted with "either actual knowledge, deliberate ignorance, or recklessness[.]" *SuperValu*, 598

U.S. at 750. "'Actual knowledge' refers to whether a person is 'aware of' information." *Id*. at 751 (citation omitted). "Deliberate ignorance" refers to defendants "who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." *Id*. And "reckless disregard" encompasses defendants "who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id*. Courts "do not look to legal interpretations that respondents did not believe or have reason to believe at the time they submitted their claims," because, in such circumstances, "[t]he FCA's scienter element refers to [a defendant's] knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed." *Id*. at 749, 755.

III. MOTION TO DISMISS

A court should not dismiss a civil action if the plaintiff has shown "a plausible entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). On a motion to dismiss, the court must "accept the truth of all well-pleaded facts and draw all reasonable inferences therefrom in the pleader's favor." *Cardigan Mountain Sch. v. N.H. Ins. Co.*, 787 F.3d 82, 87 (1st Cir. 2015) (citation omitted). Where, as here, a complaint sounds in fraud, the government must allege its claims with particularity, while "knowledge[] and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). In other words, "'intent and knowledge, may be averred in general terms' . . . if the complaint 'also identif[ies] the basis for inferring scienter[.]'" *Wilder v. Toyota Fin. Servs. Am. Corp*., 764 F. Supp. 2d 249, 260 (D. Mass. 2011) (Saris. J., adopting report and recommendation and denying motion to dismiss) (quoting *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 686-87 (2009).

FACTUAL BACKGROUND

I. RETINA PRACTICES PURCHASED EYLEA FROM DISTRIBUTORS

Eylea is a physician-administered injectable drug. As such, the distribution and purchasing of Eylea differs from that of many prescription drugs. Patients do not pick up Eylea prescriptions at local pharmacies; rather, retina practices purchase and stock Eylea, which comes in pre-filled syringes, and retina surgeons or injecting ophthalmologists administer Eylea by injecting it into a patient's eye during an outpatient office visit. Compl. ¶ 3. Eylea is thus referred to as a "buy-and-bill" drug, because retina physicians and practices incur the upfront cost of buying Eylea, and then submit claims to Medicare and other insurers for the cost and administration of the drug. *Id.* at ¶ 4.

Regeneron sells Eylea to specialty drug distributors, which sell Eylea to retina practices. *Id.* Regeneron initially entered into distribution contracts with three specialty drug distributors, Besse Medical ("Besse"), McKesson Corporation ("McKesson"), and CuraScript SD Specialty Distribution ("CuraScript"), and later with Metro Medical, a division of Cardinal Health. *Id.* Under the distribution agreements, Regeneron sells Eylea to the distributors at Eylea's wholesale acquisition cost of $1,850 per vial. Regeneron pays the distributors a "Distribution Service Fee" to compensate them for distribution services, which include, for instance, order management and processing, invoicing, inventory management, warehousing, packing and shipping, and returns processing. *See, e.g.*, Compl. ¶¶ 46-48, Ex. 2 at "Exhibit D" (2011 Besse Distribution Services Agreement). These Distribution Service Fees are either a flat fee or a percentage on each vial of Eylea sold by the distributor to a retina practice. Compl. ¶¶ 46, 48.

II. REGENERON PAID DISTRIBUTORS A SEPARATE FEE TO SUBSIDIZE EYLEA CREDIT CARD PURCHASES

As the Complaint alleges, Regeneron understood that if it did not pay separate credit card

subsidies, the distributors would have charged physician practices a higher price to use a credit card. Compl. ¶¶ 59, 73-89. For example, as Regeneron knew, Besse regularly charged customers a "cash price" for specialty drugs like Eylea; if the customer chose to use a credit card to buy that drug, the customer incurred what Besse called a "cash discount lost fee" of approximately 2.4% to account for the credit card processing fees. *Id.* at ¶ 75. Besse's standard invoices to customers for Eylea—and to Regeneron for the credit card subsidies—stated that prices "reflect a discount for payments received by cash, check, money order, EFT or similar means" and that "[p]ayments by credit card will not receive this cash discount." *Id.* at ¶ 76. In fact, it is undisputed that Regeneron's credit card subsidies lowered the amounts Eylea customers paid when using credit cards. Regeneron acknowledges that its credit card subsidies "facilitate[] maintaining a single cash-or-credit price" and that "reimbursing that cost . . . ensures that physicians pay *the same price* no matter what method they use." Mem. at 19 (emphasis in original). Regeneron admits it made the payments because "Regeneron did not want to impose a surcharge for accepting credit cards[.]" *Id.* at 24.

The Complaint further alleges that Regeneron paid credit card subsidies to ensure distributors did not charge that higher amount to customers, not for a distribution "service." Compl. ¶¶ 49-51, 77, 79-80, 101. Regeneron's subsidies simply shifted responsibility for the higher cost from Eylea purchasers to Regeneron. *See* Mem. at 24 ("*So as long as Regeneron did not want to impose a surcharge for accepting credit cards*, either Regeneron or its distributors would have to cover the processing fee as an expense[.]") (emphasis added). Regeneron included specific language in its distribution agreements that required distributors to accept credit cards from physician customers on the condition that Regeneron would cover processing fees. Compl. ¶¶ 49-51. Thus, when (and only when) Regeneron reimbursed distributor credit

card fees, distributors charged the cash price to customers using credit cards. *Id.* at ¶¶ 73-84. The unwritten—but explicitly understood and enforced—purpose of these payments was to ensure that distributors would not charge Eylea customers more to use a credit card. *Id.*

Regeneron carefully tracked how much it paid on behalf of each customer that used a credit card to purchase Eylea: Besse and the other distributors invoiced Regeneron on a monthly basis for the credit card subsidies, and, at Regeneron's request, provided backup spreadsheets detailing the amount Regeneron paid on behalf of each customer for each Eylea purchase. *Id.* at ¶¶ 8, 62-66. The monthly expense to Regeneron often amounted to millions of dollars. *See, e.g.*, *id.* at ¶ 63 (showing "Dec 2019 Eylea CC Fees" of "$4,791,504.87.").

Regeneron's credit card subsidies *directly* lowered the price of Eylea for customers that used credit cards. For example, in the absence of Regeneron's payments, an Eylea customer would have paid $44.40 more per unit of Eylea for a credit card purchase at Besse in July 2013. *See id.* at ¶ 75. In turn, if a customer received 2% "cash back" on their Eylea purchases, they received an additional $37 per unit. *See id.* at ¶ 58.

III. REGENERON KNEW THE CREDIT CARD SUBSIDIES WERE PRICE CONCESSIONS

Regeneron does not dispute that it failed to include credit card subsidies in its Eylea ASP reports—it disputes whether it was required to, and whether it knew it needed to. The Complaint alleges just that. Regeneron knew, prior to Eylea's launch, that distributors accepted credit cards for expensive products like Eylea and Lucentis (Eylea's largest branded competitor) but that they charged more for those credit card purchases. Compl. ¶¶ 77-80, 85-87. Regeneron knew that Eylea customers were profit-driven and paid close attention to margins on Eylea and competing products. *Id.* at ¶¶ 10, 54-55, 58, 80-83, 85-89. Regeneron knew that the ability to

use credit cards without a fee was important to Eylea customers and that cash back and other rewards had significant monetary value to customers. *Id*.

Regeneron specifically agreed to pay distributors' credit card costs so that they would charge customers less when customers used a credit card to purchase Eylea. *Id*. at ¶¶ 77-80; 85-87. As one Regeneron employee noted, it was a "big deal" for certain customers not to be "charge[d] more for a credit card payment." *Id.* at ¶ 77. High-ranking executives at Regeneron were aware of the value that customers placed on the ability to use credit cards without incurring an additional expense. *Id.* at ¶¶ 79; 81-83, 88-89. When one distributor added a 2.5% charge to the "cash only" price for a credit card customer, Robert Davis, Regeneron's then-Senior Director of Trade, Reimbursement and Managed Markets, asked that the distributor "correct" the issue "asap" because Regeneron "cover[s] your credit card pass thru costs[.]" *Id.* at ¶ 79. The Complaint alleges Regeneron knew the purpose of the payments was to lower customers' Eylea costs and communicated with distributors to enforce that agreement. *Id*. at ¶¶ 76-80.

Regeneron thus knew its credit card subsidies—which exceeded $250 million to a single distributor over 10 years—were price concessions. *Id*. at ¶¶ 2, 73-89. Regeneron's failure to report them as price concessions, which would have lowered Eylea's ASP, was consistent with the Company's commercial strategy to keep Eylea's reported ASP inflated and stable. *Id*. at ¶¶ 112-122. By keeping Eylea's ASP stable, Regeneron could—and did—promote Eylea as a more stable financial option for retina surgeons than its main competitor, whose ASP dropped over time, thereby lowering payments for the drug. *Id.* at ¶¶ 117-118, 121. Regeneron knew its failure to report the credit card subsidies as price concessions in Eylea's ASP directly inflated Medicare payment rates for Eylea claims. *Id*. at ¶¶ 129-131.

Regeneron also knew the credit card subsidies were not BFSFs because they failed multiple prongs of the definition of BFSFs, as memorialized in its own standard operating procedures ("SOPs"), and a third-party consultant specifically told Regeneron that the "Credit Card Fees" were not a "TYPE OF SERVICE [that] COULD BE BFSF[.]" *Id.* at ¶ 91-111.

ARGUMENT

Because the Complaint and the Consolidated Complaint plead each element of the FCA counts and all elements of unjust enrichment with the requisite particularity, and for the reasons set forth below, the Court should deny Regeneron's Motion.

I. THE COMPLAINT PLEADS ALL ELEMENTS OF AN FCA VIOLATION

The Complaint adequately pleads that Regeneron submitted false Eylea ASP reports to CMS, that Regeneron acted knowingly under the FCA, and that Regeneron caused the submission of false claims at inflated rates. Regeneron's Motion is replete with novel factual assertions inconsistent with the allegations in the Complaint, including the repeated contention that there was a "single cash-or-credit" price for Eylea. The Court need only determine whether, accepting the Complaint's allegations as true, the United States has sufficiently stated a claim.

A. The Complaint Alleges, With Particularity, That Regeneron's ASP Reports Were False

The Complaint adequately alleges that Regeneron's credit card subsidies were price concessions that Regeneron failed to include in Eylea's ASP. The subsidies were not for some purported distribution "service" as Regeneron claims. Rather, the express purpose of Regeneron's payments was to lower the cost of Eylea to customers. The Complaint alleges that Regeneron's failure to include these price concessions in the ASP reports it submitted to CMS fraudulently inflated Eylea's ASP, and thus improperly increased Medicare payment rates for Eylea. Nothing more is required at this stage.

1. *Regeneron's Payments Were Price Concessions*

The Complaint alleges with particularity that Regeneron's payments were price concessions that Regeneron should have incorporated into its Eylea ASP reports. Regeneron's conduct fits squarely into the basic definition of a price concession: Regeneron paid to lower the price of Eylea for credit card customers. The Complaint alleges, and Regeneron does not dispute, that absent Regeneron's payments, distributors would have charged those physician customers a higher price (for example, $44.40 more per vial of Eylea on a per-unit cost of $1,850, or 2.4% more than the "cash price," as set forth in Compl. ¶ 75), and that the distributors charged Eylea customers a lower price *only* because of Regeneron's payments.

Faced with the fundamental simplicity of this business arrangement, Regeneron adopts an artificially narrow reading of the ASP regulations. Mem. at 15. CMS regulations, authorized by statute, require manufacturers to report *all* price concessions, not just the enumerated categories. 42 C.F.R. § 414.804(a)(2)(i). As described above (*supra* at Legal Background, Section I), in 2006, CMS exercised its statutory authority to require manufacturers to deduct all price concessions from their ASP reporting, and to clarify that price concessions "include" the enumerated categories.[1] This regulation has the force and effect of law. *See Perez v. Mortg.*

[1] Regeneron's citation to *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 65 (D. Mass. 2011) is both incorrect and misleading. Mem. at 14. *Westmoreland* references the correct standard set forth in the regulation: "*Manufacturers are required to 'deduct price concessions'* from the numerator of this mathematical equation, *which include*' certain categories." *Id*. (emphasis added), citing 42 U.S.C. § 1395w–3a(c)(3); 42 C.F.R. § 414.804(a)(2)(i). *Westmoreland* did *not* "hold[] that a manufacturer need not include in ASP an alleged price concession that is 'not explicitly mentioned in the statute as a type of price concession,'" as Regeneron incorrectly claims. Mem. at 14. Rather, the court observed that "Overfill is not explicitly mentioned in the statute as a type of price concession." *Westmoreland*, 812 F. Supp. 2d at 65. The holding was limited to the context of drug overfill, *i.e.*, when the volume of drug slightly exceeds the amount indicated in the labeling to permit withdrawal and administration of the necessary amount. The court found that CMS properly determined overfill is not a price concession because it is not a cost to the purchaser and the additional product

Bankers Ass'n, 575 U.S. 92, 96 (2015) ("Rules issued through the notice-and-comment process . . . have the force and effect of law.") (internal quotation omitted).

The use of mandatory language ("*must* deduct price concessions"), combined with the nonexclusive verb "includes" in reference to the enumerated categories makes clear that manufacturers must deduct *all* price concessions, including *but not limited to* the types Congress provided in the statute. *See, e.g., Fed. Land Bank of St. Paul v. Bismarck Lumber Co.*, 314 U.S. 95, 100 (1941) ("[T]he term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle."); *Pfizer, Inc v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67, 76 (2d Cir. 2022), *cert. denied sub nom. Pfizer Inc. v. Dep't of Health & Hum. Servs.*, 143 S.Ct. 626 (2023) (holding that "including" preceded "merely non-exhaustive examples" and noting that "include" is "usually a term of enlargement, and not of limitation.") (citation omitted). Regeneron's argument that manufacturers are not required to report price concessions beyond the categories mentioned in 42 U.S.C. § 1395w-3a(c)(3) is antithetical to both the plain reading of the regulations and foundational principles of statutory interpretation. In short, 42 C.F.R. § 414.804(a)(2)(i) cannot reasonably be read to limit price concessions to the enumerated categories in § 414.804(a)(2)(i)(A)-(E).

Curiously, Regeneron does not address the language in the regulation requiring deduction of all price concessions from ASP. Mem. at 1-2 (arguing "Plaintiffs' theory is foreclosed by the plain text of the ASP statute."). Regeneron simply ignores the plain text of the applicable regulation, which was expressly authorized by statute and implemented following notice and

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cannot be billed to Medicare. *Id*. at 65-66 (citing 75 Fed. Reg. 73,170, 73,466–67 (Nov. 29, 2010)). Indeed, CMS implemented specific regulations to that effect to "clarify" its policy. *Id.* at 66. Accordingly, the court held, as determined by CMS, that overfill should not be reflected in ASP because it was not a price concession, not because the statute did not explicitly mention it as a type of price concession. *Id.* at 67-68.

comment, and instead argues, incorrectly, that CMS "has never used [its] authority" to expand reportable price concessions and that CMS has "declined" to expand the list of reportable price concessions. Mem. at 8. And, even if Regeneron's argument had merit, Regeneron's credit card subsidies would then be reportable price concessions because they were rebates to distributors. The Complaint alleges that Regeneron sold drugs to distributors at an initial price, then effectively lowered that price by reimbursing credit card processing fees subsequently incurred by those distributors. Compl. ¶¶ 49-51, 59-69.

Instead, Regeneron argues that its ASP reports cannot be false because it allegedly "reasonably interpreted th[e ASP] scheme" to conclude that its credit card subsidies were not price concessions. Mem. at 32. Regeneron argues its position is based on CMS guidance permitting manufacturers to make "reasonable assumptions" in calculating ASP. *See* Mem. at 9-11, 29-32. Yet the plain text of the ASP regulation unambiguously requires the reporting of all price concessions, and so conflicts with Regeneron's alleged interpretation that manufacturers must only deduct "six specific categories of price concessions." Mem. at 16. As such, Regeneron's arguments about a lack of "fair notice" regarding the meaning of the applicable ASP regulations, Mem. at 30, and a lack of "guidance," see, *e.g.*, Mem. at 8-10, concerning the applicable rule are simply incorrect. Moreover, Regeneron's argument invites a series of factual questions that contradict or exceed the scope of the Complaint's allegations, including whether the company actually interpreted the ASP "scheme" as it says it did, whether it actually made these assumptions at the time, and whether they were actually "reasonable."[2] The same is true as

[2] Regeneron appears to further argue its ASP reporting was reasonable in part because a different treatment of the credit card subsidies could impact its "average manufacturing price" ("AMP") reporting, which could impact certain rebates. Mem. at 30-31. Both Medicare and the intervening States, however, reimbursed Eylea (which is typically administered and billed by retina practices, Compl. ¶ 4), based on ASP; AMP, on the other hand, is defined as applying to

to the factual basis of any potential "good faith" defense. *See* Mem. at 11-12. Whether Regeneron acted reasonably is not relevant to falsity, but rather goes to its scienter, as discussed in Section C, *infra*, and does not inform the correct statutory interpretation.

CMS's inclusion of the BFSF definition in the ASP regulations, 42 C.F.R. § 414.804(a)(2)(ii), further belies Regeneron's cramped reading. The regulatory test for BFSFs is inapposite to the kinds of price concessions Congress initially listed in the statute because it is explicitly designed to apply to "service fees," not to discounts for which there is no service rendered in exchange. For example, there is no "bona fide, itemized service" involved in a "prompt pay discount" or a "cash discount"—those are merely price concessions paid to incentivize speedy remittance of payment or use of cash rather than credit, respectively. Instead, as CMS explained during its rulemaking, the BFSF definition was implemented to distinguish price concessions from service fees that are consideration for specific services rendered on behalf of the manufacturer. *See* 71 Fed. Reg. 69,624, 69,668 (Dec. 1, 2006) (explaining the purpose was to differentiate "situations in which we believe a fee paid is compensation for services rather than a price concession for drugs."). If, as Regeneron argues, the agency had not expanded the universe of price concessions originally listed in the ASP statute, then there would be no need to distinguish BFSFs, as the statute makes no reference to "service fees" at all.

Regeneron also attempts, unconvincingly, to thread a semantic needle that its subsidy payments are somehow different from price concessions. Mem. at 18-20. Regeneron cites to a

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sales concerning "retail community pharmacies," 42 U.S.C. § 1396r–8(k)(1). There was thus no "quandary" for Regeneron, Mem. at 31, concerning its AMP and ASP reporting for Eylea. Furthermore, the AMP case cited by Regeneron supports the concept that manufacturers cannot manipulate price reports for their own benefit. *See, e.g., United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019) (denying motion to dismiss and holding "[w]hat constituted bona fide services fees for purposes of calculating AMP was not ambiguous.").

panoply of state laws that prohibit merchants from framing different cash and credit prices as surcharges on customers. Mem. at n.3. But courts interpreting these laws affirm the obvious: there is no substantive difference between a subsidy and a discount. *See, e.g., Italian Colors Rest. v. Becerra*, 878 F.3d 1165, 1176 (9th Cir. 2018) (referring to the "mathematical equivalency between surcharges and discounts"). Indeed, courts have sustained First Amendment challenges to these state surcharge laws under the theory that they regulate the communication of prices rather than conduct itself, because the laws permit a discounted cash price but prohibit a mathematically-equivalent higher credit card price. *See, e.g., id.*; *Dana's R.R. Supply v. Att'y Gen., Fla.*, 807 F.3d 1235, 1239 (11th Cir. 2015) (striking down Florida's no-surcharge law as an abridgement of free speech, stating "[t]autologically speaking, surcharges and discounts are nothing more than two sides of the same coin; a surcharge is simply a 'negative' discount, and a discount is a 'negative' surcharge." Accordingly, "a merchant who offers the same product at two prices," a lower cash price and a higher credit card price, "is allowed to offer a discount for cash while a simple slip of the tongue calling the same price difference a surcharge runs the risk of being fined and imprisoned."). Common experience regarding dual cash-or-credit pricing also contradicts Regeneron's position. *See, e.g., Bautista v. Valero Mktg. & Supply Co.*, 322 F.R.D. 509, 512 (N.D. Cal. 2017) (concerning gas "stations that practice 'split-pricing' by charging higher fuel prices on credit transactions and lower fuel prices on cash transactions."); *see also Kurimski v. Shell Oil Co.*, No. 21-80727-CV, 2022 WL 2913742, at *1 (S.D. Fla. June 30, 2022). In any event, whether Eylea distributors' higher credit card prices complied with the state laws Regeneron cites is irrelevant. On the alleged facts, Regeneron's credit card subsidies lowered the price to the customer, thereby constituting price concessions for purposes of its ASP reporting obligations under federal law.

Regeneron next constructs a straw man by arguing that credit card *rewards* are not reportable price concessions. The government alleges that the credit card subsidies *Regeneron paid* were reportable price concessions, not that the credit card rewards *Eylea customers received* were such concessions. The lucrative benefits physicians received because of Regeneron's scheme, including hundreds of millions of dollars in cash back rewards, explain Regeneron's motive in making hundreds of millions of dollars' worth of credit card subsidy payments: Regeneron knew its customers wanted them. *See, e.g.*, Compl. at ¶ 2 ("Regeneron paid [credit card subsidies] so that doctors and retina practices that purchased Eylea could use credit cards at no additional cost and obtain hundreds of millions of dollars in 'cash back' rewards and other credit card benefits on their Eylea purchases.").

Oddly, Regeneron argues that the government's position is tantamount to accusing "millions of Americans [who] seek reimbursement for expenses paid for by credit card without accounting for rewards or cash-back . . .[of] committing mail or wire fraud." Mem. at 26. But the average American's credit card transactions are not subject to price reporting requirements, and "pizza parlor" purchases are not paid for by the Medicare Trust Fund. Moreover, removed from the regulatory context at issue here, who pays credit card fees and who is entitled to credit card rewards is simply a contractual matter that is of no moment to the FCA. And of course, this specious argument is silent as to the most important element of any mail and wire fraud charge: intent to defraud.

Finally, relying on *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 87 (1st Cir. 2012), Regeneron argues that "statements as to conclusions about which reasonable minds may differ cannot be false." Mem. at 3, 27-28, 33. That grossly overstates the holding in *Brigham*, a case involving allegedly false data underpinning claims for payment. In

its summary judgment opinion, the First Circuit considered the defendant's argument that "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *Id.* at 87 (internal quotation omitted). The court nevertheless held that there was a dispute of material fact concerning whether a grant application relied on falsified data—in other words, if the data were falsified, the question is not one of how to exercise scientific judgment. *Brigham*, 678 F.3d at 88. Similarly, in this case, the Complaint alleges that Regeneron's ASP reports were false because the Company knowingly failed to incorporate the credit card subsidies as price concessions in its calculation of ASP. Put differently, whether paying a customer's credit card fees constitutes a price concession is not a matter of subjective opinion—it either lowered the price or it did not. Regeneron's arguments that the credit card subsidies were not price concessions are unavailing.

2. *The Complaint Alleges Regeneron's Payments Were Not BFSFs*

As set forth in further detail below, the Complaint alleges with particularity that the credit card subsidies were not for "service fees" at all, much less that they satisfy the four regulatory requirements to qualify as "bona fide" service fees. Compl. ¶¶ 49-51.

a. Regeneron's Credit Card Subsidies Do Not "Represent Fair Market Value For A Bona Fide, Itemized Service Actually Performed On Behalf Of The Manufacturer"

The first two requirements for a fee to qualify as a BFSF are that it must (1) "represent fair market value [(2)] for a bona fide, itemized service actually performed on behalf of the manufacturer." 42 C.F.R. § 414.802. The Complaint alleges that Regeneron's credit card subsidies failed these requirements because they were not consideration for any service performed on behalf of Regeneron but instead were price concessions Regeneron paid to distributors on behalf of *customers* to lower the prices they paid for Eylea.

Regeneron's factual assertions to the contrary are irrelevant to the Court's decision on a motion to dismiss, as they contradict the Complaint's allegations, and altogether incorrect. The credit card subsidies did not compensate distributors for accepting payment via credit card; as Regeneron acknowledges, distributors would have accepted credit cards from customers without Regeneron's subsidies—distributors simply would have charged customers more to use them. *See* Mem. at 24; Compl. ¶¶ 96, 101. The purported "service" provided in exchange for the subsidy was not the credit card payment processing itself, *i.e.*, the "enormously complicated" "13-step process" that financial institutions performed. Mem. at 6, 22. Instead, Regeneron paid the subsidies to cause distributors not to charge more for credit card use, thereby lowering the price for credit card customers. The "service" for the credit card subsidy was thus nothing more than a windfall for Regeneron's credit-card using customers, not a bona fide distribution service, which fundamentally distinguishes the fee reimbursements from "ordinary shipping fees" that "enable[] Regeneron to get its products to customers[.]" Mem. at 23. Similarly, Regeneron's argument that credit card transactions provide "a valuable service to merchants and customers alike[,]" Mem. at 22, underscores that the transactions were not on Regeneron's behalf, as it was neither the merchant nor the customer in the Eylea purchase transactions.

The United States does not allege, as Regeneron mischaracterizes, that "any service that benefits Regeneron's customers is not 'on behalf' of Regeneron[.]" Mem. at 23 n.12. Rather, the United States alleges, and Regeneron cannot plausibly dispute, that a "service" that does nothing more than financially benefit certain customers by lowering their purchase price is not actually a distribution service. Indeed, while Regeneron argues that it pays for "other services" like "nonstandard shipping . . . at those services' cost," *id.* at 6, Regeneron's distribution agreements make clear that benefits like expedited shipping are billed to Regeneron only if

Regeneron requested them (*i.e.*, they were for Regeneron's benefit) and otherwise they were billed to the physician customer if the customer requested them (*i.e.*, they were for the customer's benefit). *See, e.g.*, Compl. Ex. 2 at 30-31; Compl. Ex. 4 at 28-29.

b. Regeneron's Subsidy Payments Were Not In Exchange For A Service Regeneron Would Otherwise Perform (Or Contract For)

To be a BFSF, a fee must also be for a "service . . . the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement[.]" 42 C.F.R. § 414.802. The Complaint alleges both that Regeneron could not otherwise perform or contract for the purported "service" of causing distributors to waive higher costs for Eylea credit card customers, and that this "service" was wholly unnecessary for the distribution of Eylea. Regeneron's interpretation of this prong appears to read out any degree of necessity to the process of distribution. Regeneron notes, for example, that "[s]o as long as Regeneron did not want to impose a surcharge for accepting credit cards, either Regeneron or its distributors would have to cover the processing fee as an expense[.]" Mem. at 24. But "not want[ing] to impose a surcharge" is not a distribution service at all—it is a windfall for Eylea customers. Regeneron likewise mischaracterizes the fees as a "quintessential expense," Mem. at 24, but the fact that Regeneron might not "want" distributors to charge more for credit cards does not render a subsidy "part of the process of distribution" of Eylea. Mem. at 17. CMS has stated "we interpret these [BFSF] elements . . . to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with *the efficient distribution of drugs*." *See* 71 Fed. Reg. 69,624 at 69,667-68 (emphasis added). But, as alleged, the credit card subsidies were paid to lower the price of Eylea, not to make Eylea distribution more efficient.

Regeneron seems to argue that "distribution services" should encompass any "reimburs[ed] expenses that its distributors actually incur as part of the process of

distribution"—even if they confer significant monetary value to customers, and they are unnecessary for the distribution of the drug. Mem. at 17. Regeneron's interpretation would lead to the absurd outcome that any benefit Regeneron wished to provide to customers, no matter how attenuated from the actual process of distributing drugs, such as a free car the product is delivered in or free lunches or gifts for office staff receiving a delivery, could be framed as a "distribution service" so long as distributors actually incurred the expense and sought reimbursement from Regeneron. Regeneron's elastic definition of this prong of the BFSF test would render it a nullity.

Regeneron also attempts to argue that this prong is satisfied if Regeneron would have contracted with credit card companies for credit card processing if Regeneron had sold Eylea directly to doctors and retina practices. Mem. at 24. But Regeneron provides no support for evaluating its subsidy payments outside of their contractual context. As CMS explained, the purpose of the definition was to distinguish BFSFs from price concessions. *See* 71 Fed. Reg. at 69,668 (explaining the purpose was to differentiate "situations in which we believe a fee paid is compensation for services rather than a price concession for drugs."). The appropriate inquiry to evaluate the credit card subsidies is to consider what Regeneron would or could have done in the context of its actual agreements with distributors had it not paid the credit card subsidies. Compl. ¶¶ 49-51. Evaluated in that context, and unlike for shipping fees and other distribution services, Regeneron had no way to subsidize Eylea customers' credit card purchases other than to rebate distributors for the credit card processing fees. There is no evidence that Regeneron would (or even could) have contracted directly with credit card companies to waive those fees, and it would be inconsistent with the relationship between credit card companies and merchants, because Regeneron was not a party to the transaction occurring between distributors and

customers.[3]

c. Regeneron's Subsidy Payments Were Passed On To Customers

The BFSF definition requires that the credit card subsidies are "not passed on in whole or in part to a client or customer[.]" 42 C.F.R. § 414.802. The Complaint alleges with particularity that Regeneron's credit card subsidies were passed on to Eylea customers. Compl. ¶¶ 62-65, 73-86, 103-106. The Complaint details how Regeneron required distributors to provide records that allowed Regeneron to monitor the credit card transaction fees on a per-transaction basis to determine, down to the penny, how much it needed to rebate distributors. Compl. ¶¶ 62-65, 105. The Complaint alleges that Regeneron ensured the payments subsidized Eylea purchases. *See, e.g.*, Compl. ¶ 77 (2011 email stating, "We will pay pass thru fees so the 3 distributors will not charge extra to offices [customers].").

Regeneron's effort to reframe the issue by arguing that its credit card subsidies were not passed through to customers because "the credit card processing fee *itself* was [not] passed on to doctors[,]" Mem. at 25 (emphasis in original), would require the Court to disregard the basic economics of the business transaction. It is irrelevant that Regeneron did not cut Eylea customers a check or require distributors to charge customers a fee and then reimburse them using Regeneron's funds: Regeneron rebated distributors to save customers from paying the higher credit card price. Regeneron's reimbursements were functionally the same as Regeneron directly paying customers to cover the higher price they would otherwise have incurred when using credit cards. Compl. ¶ 103. Indeed, that was the express purpose of Regeneron's

[3] The fact that some doctors would have used credit cards to purchase Eylea "*even if*" Regeneron had not paid the credit card subsidies, Mem. at 24 (emphasis in original), simply underscores that the subsidies were price concessions.

payments.[4] Compl. ¶¶ 73-86. To hold otherwise, as Regeneron proposes, would elevate form over substance and only encourage gamesmanship in price reporting.

B. The Complaint Alleges Regeneron Submitted False ASP Reports That Caused And Were Material To The Submission Of False Eylea Claims

The Complaint alleges Regeneron submitted false ASP reports and caused the submission of false claims for Eylea, including those specifically identified in the Complaint. Compl. ¶ 131. Those claims are directly tied to Regeneron's fraudulent conduct: Regeneron failed to incorporate in its calculations of ASP the hundreds of millions of dollars in price concessions it provided to distributors and Eylea purchasers who used credit cards. By reporting a false and inflated ASP to CMS, Regeneron caused Medicare to pay for Eylea claims at an inflated rate. Regeneron submitted these false ASP reports "knowing that [Eylea customers] would present claims to [the government] which will be reimbursed based on a formula that utilizes the inflated price to determine the appropriate reimbursement amount[.]" *Mylan Lab'ys*, 608 F. Supp. 2d 127, 144-145 (D. Mass. 2008) (denying motion to dismiss a complaint alleging, under the Massachusetts FCA analogue, the defendant submitted false price reports that caused false claims to be submitted at inflated payment amounts). Regeneron thus submitted false ASP reports that caused and were material to the submission of false claims for Eylea.

The relevant allegations in this case are analogous to those in the Average Wholesale Price ("AWP") litigation previously before this Court, in which the Court correctly held that claims "predicated on an underlying fraudulent pricing scheme" are false "although the claim

[4] Regeneron points to agency guidance that manufacturers "may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity." Mem. at 24, quoting 71 Fed. Reg. at 69,669. Yet, the Complaint alleges Regeneron knew exactly how much it was paying as a price concession for each customer on each purchase. Compl. ¶¶ 8, 62-63, 65-66.

itself may not contain a fraudulent price[.]" *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 172-73 (denying the motion to dismiss the claims brought under the California False Claims Act, which is "modeled after the federal counterpart"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 19 (denying "the motion to dismiss [federal FCA claims] because there was no false claim[.]") (citing *id.* at 172-175); *see also United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC et al.*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009) (denying motion to dismiss FCA claims where "Defendants reported false and inflated AWPs and WACs for certain drugs knowing that Medicaid relied on these prices to set reimbursement rates [and a]s a result, Medicaid paid excessive reimbursement for Defendants' drugs[.]") (internal citations omitted). The Complaint alleges Regeneron submitted false Eylea price reports to CMS that set the basis for Eylea payments. *See, e.g.*, Compl. ¶ 2. Regeneron argues that "quarterly ASP submissions do not 'request . . . money or property' from the government[,]" Mem. at 34, but that was also true of the false pricing reports submitted by AWP defendants, who submitted inflated AWPs to third-party pricing compendia, thereby causing the submission of false claims by third-parties. *See, e.g.*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 14 ("The crux of the government's complaint is that [the defendant] fraudulently inflated the . . . AWP . . . that it reported to drug pricing compendia used by the government to set reimbursement rates for pharmaceuticals, and that as a result of the publication of these inflated prices, the government over-paid medical providers for [the defendant]'s drugs."). The logical fallacy of Regeneron's argument is that there could never be FCA liability based upon a false ASP (or AWP) report, no matter how fraudulently inflated. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 173 ("Defendants' interpretation that they have *carte blanche* to publish sky-high prices unmoored from the

acquisition costs of providers leads to absurd results.") (citations omitted). Cognizant of this Court's precedents in the AWP matters, and their obvious applicability here, Regeneron attempts to distinguish the AWP matters from this one. Mem. at 32. But the allegations are indeed parallel—both involve fraudulent price reports that inflated government drug payment rates and thereby caused the submission of false claims to government programs at those inflated rates.

Inflated claims based on false price reports are false or fraudulent under common law—and the FCA. Because Congress did not define what constitutes a "false" or "fraudulent" claim under the FCA, courts look to the common-law meaning of the terms. *Escobar*, 579 U.S. at 187 ("[T]he term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud.") (internal quotation omitted). This Court has found that inflated price reports can cause fraudulent claims under state and federal common law—and give rise to FCA liability—even in cases where the false price reports were submitted to third parties. *See In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-CV-12257-PBS, 2007 WL 1051642, at *12–14 (D. Mass. Apr. 2, 2007) (denying motion to dismiss fraud claims brought under New York common law: "the defendant (1) made a material false statement; (2) knowing that the statement was false; (3) acting with intent to defraud; that plaintiff (4) reasonably relied on the false representation and (5) suffered damage proximately caused by the defendant's actions.") (internal quotation omitted); *In re Pharm. Indus. Average Wholesale Price Litig*., 685 F. Supp. 2d 186, 209-10 (D. Mass. 2010) (denying defendant's motion for summary judgment on common law fraud claim); *see also Marcus v. AT&T Corp.*, 138 F.3d 46, 57 n.2 (2d Cir. 1998) (noting the "appellants also raise a claim of federal common law fraud, in addition to New York state common law fraud. Because the standards for fraud are practically identical, we consider these claims together."); *MSP Recovery Claims, Series LLC v. Abbott Lab's*, No. 19-CV-21607

(FLW), 2021 WL 2177548, at *12 (D.N.J. May 28, 2021) (holding defendant laboratory's "contrived fictitious AWPs" constituted material misrepresentations sufficient to support a common law fraud claim) (collecting cases, citations omitted); *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, No. SA-14-CV-00212-XR, 2024 WL 2244818, at *4 (W.D. Tex. May 1, 2024) (denying defendant's motion for summary judgment on allegations of false claims based on inflated AWP reports and affirming "[t]he FCA reaches anyone who knowingly assists in causing the Government to pay claims grounded in fraud, without regard to whether that person has direct contractual relations with the government.") (internal quotations omitted).

As in the AWP matters, and as the Complaint alleges, the claims "ophthalmologists submit seeking reimbursement for EYLEA," Mem. at 34, are false or fraudulent. These claims were false because they were paid at fraudulently high rates. Compl. ¶¶ 129-131. There is also a separate and distinct basis for falsity: doctors and retina practices certified that claims for Eylea complied with Medicare regulations, which was untrue because of Regeneron's misconduct. *See* Compl. ¶ 23; Sample Form CMS-1500 – Health Insurance Claim Form, *available at* https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf (including certification claim complies with "all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment"); *see also* Form CMS-855I – Medicare Enrollment Application (Physicians and Non-Physician Practitioners), *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf ("I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions[.]"). These certifications were material to Medicare's payment decisions. *See Escobar*, 579 U.S. at

190. Regeneron argues that the claims were not false under *Escobar*, because "while physicians' reimbursement requests obviously do [request payment from government programs], they just as obviously do *not* certify compliance with the ASP statute when they seek reimbursement based on ASP." Mem. at 34-35 (emphasis in original). But Regeneron's reading of *Escobar* is far too narrow. Not only does *Escobar* support the principle that fraudulent claims are false under the FCA, but as with an AKS-tainted claim, the Eylea claims at issue—and related certifications—are false even if the claims submitters were unaware of the fraud. *Hutcheson,* 647 F.3d at 390 ("The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct.").

Regeneron is correct that the *sine qua non* of an FCA case is a material connection between a defendant's fraud and the payment of money by the government. Mem. at 33. That is *precisely* what the Complaint alleges, and the cases Regeneron cites are inapposite. For instance, in *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34 (D. Mass. 2014), the relator attempted to argue that false promotional statements rendered certain claims false. The First Circuit upheld summary judgment against the relators because they failed to connect the alleged false statements to a payment for any specific claims. *Id.* at 59 ("After six years of litigation, relators' only proffered evidence of actual false claims was aggregate data[.]"). In this case, however, the Complaint identifies a material and direct connection between Regeneron's false ASPs and the specific alleged false claims. *See Hutcheson*, 647 F.3d 377, 394-95 ("[Defendant's] argument that Medicare would excuse these violations because of a bureaucratic mechanism . . . impermissibly cabins what the government may consider material.").

The other cases Regeneron cites are similarly inapposite. In *New York v. Amgen*, the First Circuit again held that an FCA plaintiff must connect an alleged fraud with a payment by the applicable government program—in that case holding that kickback-tainted claims would be false for six of seven state Medicaid programs. 652 F.3d 103, 116 (1st Cir. 2011).[5] Similarly, in *United States ex rel. Ge v. Takeda Pharm. Co.*, the relator alleged a "fraud-on-the-FDA" but the First Circuit held that the relator "made no attempt . . . to allege facts that would show that some subset of claims for government payment for the four subject drugs was rendered false as a result of [the defendant's] alleged misconduct." 737 F.3d 116, 121, 124 (1st Cir. 2013). And in *United States ex rel. Grant v. United Airlines Inc.*, the Fourth Circuit found the relator's complaint "fails to allege how, or even whether, the bills for these fraudulent services were presented to the government and how or even whether the government paid United for the services." 912 F.3d 190, 198 (4th Cir. 2018). The deficiencies identified in these cases are absent here—the Complaint alleges the obvious connection between Regeneron's conduct and the false claims.

Lastly, Regeneron's suggestion that the government "cannot prevail unless the 'claim' the third party was fraudulently induced to submit is itself false or fraudulent" is misguided. Mem. at 36. It is well-established that even if a claim is not false on its face, it is actionable under the FCA if it is "grounded in fraud." *Hutcheson*, 647 F.3d at 390 (quoting *Hess*, 317 U.S. at 544-45) (1943)). As the D.C. Circuit has explained:

> Under longstanding Supreme Court precedent, a violation of the FCA occurs when a person fraudulently induces the government to enter a contract and later submits claims for payment under that contract. *See* [*Hess*, 317 U.S. 537]; *see also U.S. ex rel. Bettis v. Odebrecht Contractors of Cal., Inc*., 393 F.3d 1321, 1326–27 (D.C.

[5] Regeneron argues "the First Circuit . . . holds that even where fraudulent practices induced third parties to submit claims for payment, the underlying fraud does not carry over to the claims themselves." Mem. at 36, citing *Amgen*, 652 F.3d at 111. However, the First Circuit, in *Amgen* and *Hutcheson*, in fact held the opposite: underlying fraud does carry over to fraudulent claims submitted by third parties. It is unclear why Regeneron believes *Amgen* supports that assertion.

> Cir. 2005). Although the text of the FCA prohibits only false or fraudulent claims, the Court has placed a common law gloss on the statute, interpreting it to also prohibit fraudulent inducement. This means that "each claim submitted to the Government under a contract which was procured by fraud" is false "even in the absence of evidence that the claims were fraudulent in themselves." *Bettis*, 393 F.3d at 1326.

United States ex rel. Cimino v. Int'l Bus. Mach. Corp., 3 F.4th 412, 417 (D.C. Cir. 2021). As the Eleventh Circuit recognized, "subsequent claims [can be] false 'because of an *original fraud* (whether a certification or otherwise).'" *United States ex rel. Marsteller v. Tilton*, 880 F.3d 1302, 1314 (11th Cir. 2018) (citation omitted) (emphasis in original). In this case, the Complaint alleges that Regeneron fraudulently caused Medicare to pay for Eylea at inflated rates and therefore, the Eylea claims at issue are false.

C. The Complaint Plausibly Alleges Regeneron Acted Knowingly

The Complaint alleges a clear and plausible theory, supported by detailed allegations and referencing specific documents, that Regeneron either actually knew its ASP reports were false, or acted with deliberate ignorance or with reckless disregard as to the truth or falsity of its ASP reports. As explained *infra*, these allegations more than meet the requisite pleading standard for scienter under the FCA, which can be alleged generally. 31 U.S.C. § 3729(b); Fed. R. Civ. P. 9(b). Regeneron's arguments to the contrary are, at base, requests for this Court to impermissibly draw inferences in its favor, and the fact that Regeneron disagrees with the allegations in the Complaint is both unsurprising and irrelevant.

1. *The Complaint Alleges Regeneron's Knowledge*

The Complaint sets forth allegations sufficient to satisfy the requirements for pleading knowledge under Rule 8. *See supra* Legal Background. Regeneron understood that its customers often preferred to use credit cards, including because the credit cards typically provided the physicians and their practices cash back and other credit card rewards. Compl.

¶¶ 2, 9-10, 59. Because of the high price of Eylea, many practices received hundreds of thousands, and in some cases, millions, of dollars in cash back from using their credit cards—as Regeneron knew full well. *Id*. at ¶ 10. The Complaint further alleges that by excluding the credit card subsidies from ASP, Regeneron knew it could keep Eylea's ASP—and thus the rate at which doctors were paid for the drug—stable, a business and strategic priority for the Company. *Id*. at ¶¶ 112-122. The Complaint thus provides detailed allegations that Regeneron knew the benefits of paying the subsidies and fraudulently excluded them from ASP.

The Complaint also alleges that Regeneron understood the statutory and regulatory ASP reporting regime with enough clarity to engage in substantial internal discussion of, and solicit a third-party consultant for, an analysis of whether the credit card subsidies were reportable price concessions or alternatively, BFSFs. *Id*. at ¶¶ 12, 91-111. It had internal operating procedures for conducting a BFSF analysis "to determine if the fee is for a type of service that could be a BFSF or rather is a price concession or discount." *Id*. at ¶ 92 (citing Ex. 41, at § 5.4.1.1.1). The Complaint thus alleges that Regeneron had actual knowledge of the applicable regulatory requirements, and knew that it should apply them to the issue of credit card subsidies.

Nevertheless, Regeneron undertook an analysis that was at odds with the regulatory requirements, contrary to its own internal SOPs, and wholly self-serving. *Id.* at ¶¶ 92, 98, 100-101, 108-111. The Complaint alleges that despite the requirement that a BFSF be for a service performed on its own behalf, it knew the subsidies actually paid for no legitimate service at all, and at most, for the ostensible "service" of providing a lower price to Eylea customers. *Id*. at ¶¶ 94-97. It knew that the distribution agreements already compensated distributors for all the services actually necessary to distribute Eylea, and that this additional surcharge served only to ensure the distributors did not pass the cost of credit card processing on to Regeneron's

customers—something Regeneron neither would nor could otherwise do. *Id*. at ¶¶ 94-97, 99-102. The Company also knew that the subsidies themselves were passed on to Eylea customers. *Id*. at ¶¶ 104; *see also id*. at ¶ 77 (quoting a Regeneron executive: "We will pay pass thru fees so the 3 distributors [(Besse, McKesson, and CuraScript)] will not charge extra to offices."). Regeneron knew—contrary to its litigation position—that there was no "single cash-or-credit price," and that if it did not pay the distributors the subsidies, credit card customers could not enjoy the lower cash price. *Id*. at ¶¶ 76-77, 79-80, 85-87, 96, 101, 103. And as further support for the already in-depth allegations detailing Regeneron's knowledge, the Complaint repeatedly cites to an analysis conducted by its third-party expert, Deloitte, that specifically put the Company on notice that the subsidies did not meet the regulatory criteria. *Id*. at ¶¶ 98, 102, 107. Finally, in spite of all this, Regeneron still made the strategic and financially lucrative decision to exclude the credit card subsidies from its calculation of ASP. *See id*. at ¶ 2.

The Complaint thus includes detailed factual allegations reflecting that Regeneron knew exactly what it was doing in excluding the subsidies from ASP or was at least deliberately ignorant, or reckless, in doing so. Regeneron's contention that the United States has not "plausibly plead[ed] any facts to support scienter" is thus both puzzling and untrue: these detailed allegations are the "smoke" that "support an inference of fire," Mem. at 37—an inference that must, at this stage, be drawn in the government's favor. Whether Regeneron acted in "good faith" as it asserts and implies, *see* Mem. at 11-12, 29 n.17, is a factual question that is not ripe for a motion to dismiss. *See, e.g., United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs*, 540 F. Supp. 3d 103, 117-118 (D. Mass. May 19, 2021) ("[T]he reasonableness of defendant's interpretation of the regulation and suggestions of government warnings away from that interpretation present mixed questions of fact and law best resolved by

the jury when the material facts are in dispute.") (quoting *United States ex rel. Herman v. Coloplast Corp.*, 327 F. Supp. 3d 300, 310 (D. Mass. 2018)); *United States ex rel. Kuzma v. N. Ariz. Healthcare Corp.*, No. 18-CV-8040-PCT-DGC, 2021 WL 75827, at *7 (D. Ariz. Jan. 8, 2021) (rejecting defendant's argument at motion to dismiss that scienter could not be proven in light of alleged statutory ambiguity, as there was a factual dispute as to whether the defendant's interpretation was objectively reasonable or arrived-at in good faith); *United States ex rel. Ross v. Independent Health Corp.*, No. 12-CV-299S, 2023 WL 24055, at *11 (W.D.N.Y. Jan. 3, 2023) (rejecting defendant's argument at motion to dismiss that its practice was objectively reasonable).

2. *Regeneron Misapplies the Standard And Misconstrues the Law*

Regeneron's Motion makes a series of blunderbuss attacks on the Complaint's scienter allegations that suggest the Court ought to set aside the allegations in the Complaint, consider other facts, or draw inferences in its own favor. That is not the standard. *See, e.g., Cardigan Mountain Sch.*, 787 F.3d at 87. Scienter is a fact-intensive inquiry—so much so that it is rarely ripe for ruling on a summary judgment motion, let alone upon a motion to dismiss. *See Coloplast Corp.*, 327 F. Supp. 3d at 309-10 (citing *Mylan Lab'ys*, 608 F. Supp. 2d at 154).

Regeneron's elision of the Complaint's allegations and failure to address the plausible inferences from those allegations undercuts its scienter arguments. For example, Regeneron acknowledges Deloitte's analysis that put Regeneron on notice that the subsidies failed the BFSF requirements. Mem. at 36-37. It urges the Court, however, to conclude that the document really means Regeneron conducted a BFSF analysis because the document elsewhere states "Regeneron has concluded that the actual cost of the credit card fees is in-line with common industry terms and Regeneron would otherwise incur these costs"—even though that language

references *Regeneron*'s conclusions, evidently based on "common industry terms" irrelevant to the BFSF test, and actually contradicts Deloitte's analysis. *Id*. at 37. Indeed, Alicia Pantaleo, the "Client Approver" for this document, was not aware of anything Regeneron did to "substantiate that they were BFSF." Compl. §§ 109-111. Regeneron tries to undermine the import of Ms. Pantaleo being unaware of any support for Regeneron's position, Mem. at 38, even though a plausible inference is that Regeneron was deliberately indifferent or reckless as to the falsity of the ASP reports. Finally, Regeneron suggests the Court should somehow consider and credit the absence of allegations based on Regeneron employee witness statements while ignoring the allegations in the Complaint.

The cases Regeneron cites in support are both orders on summary judgment motions, applying different standards of review to distinctive facts, and that, upon examination, actually undercut Regeneron's argument. *United States ex rel. Banigan v. Organon USA Inc.*, No. 07-CV-12153-RWZ, 2016 WL 10704126 (D. Mass. Aug. 23, 2016) ("*Banigan II*"); *United States v. Regeneron Pharms., Inc.*, No. 20-CV-11217-FDS, 2023 WL 7016900 (D. Mass. Oct. 25, 2023) ("*Regeneron Copay*"). First, in *Banigan II*, the court held that scienter was properly a question for the jury to resolve—not for the court at summary judgment. 2016 WL 10704126, at *3-4. Indeed, the court, in the earlier decision denying the defendants' motion to dismiss, repeated the Rule 9(b) standard that "knowledge, and other conditions of a person's mind may be alleged generally." *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 294, n.26 (D. Mass. 2012) ("*Banigan I*"). Notably, the *Banigan* case involved allegations arising under the Anti-Kickback Statute ("AKS"), with a higher evidentiary threshold for scienter. *See, e.g.*, *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, 500 F. Supp. 3d 345, 360 (E.D. Pa. 2020) ("The FCA's scienter element is easier to meet than the AKS's scienter element: the FCA only

requires recklessness or deliberate ignorance of illegality . . . while the AKS requires knowledge of illegality."). Second, in the *Regeneron Copay* case, another FCA-AKS case, Judge Saylor rejected Regeneron's argument at summary judgment "that the government cannot establish a knowing violation of the FCA because it lacks evidence that the relevant decisionmaker at Regeneron—the CEO, Dr. Schleifer—'knowingly' caused the submission of false claims." *Regeneron Copay*, 2023 WL 7016900 at *14. Earlier, in ruling on Regeneron's motion to dismiss, the court held that "[a] jury must make the 'difficult factual determination' of a payor-company's intent in paying or offering remuneration to a healthcare provider[.]" *United States v. Regeneron Pharms., Inc.*, No. CV 20-11217-FDS, 2020 WL 7130004, at *8 (D. Mass. Dec. 4, 2020) (citation omitted).

Next, Regeneron attempts to argue its interpretation of the law is objectively reasonable, without establishing its current arguments are the interpretation it held at the time. *See, e.g.*, Mem. at 3. The Supreme Court rejected precisely this type of scienter argument in *SuperValu*:

> Based on the FCA's statutory text and its common-law roots, the answer to the question presented is straightforward: The FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed. And, even though the phrase 'usual and customary' may be ambiguous on its face, such facial ambiguity alone is not sufficient to preclude a finding that respondents knew their claims were false.

SuperValu, 598 U.S. at 749.[6] How Regeneron subjectively and contemporaneously interpreted the law, the list of reportable price concessions in 42 U.S.C. § 1395w-3(c)(3), and whether it acted in "good faith" as it asserts, Mem. at 11, 29 n.7, are questions of fact inappropriate for resolution at the pleading stage. Rather, the Court should credit the Complaint's well-pleaded allegations that Regeneron did *not* hold the "interpretation" it proffers in support of its motion.

[6] *SuperValu* also concerned a CMS drug price reporting regulation. The Supreme Court found it enforceable under the FCA although arguably "ambiguous on its face[.]" 598 U.S. at 749.

See, e.g., Compl. ¶ 92 (quoting Regeneron's BFSF SOPs acknowledging the need "to determine if a fee is for a type of service that could be a BFSF *or rather is a price concession or discount*.") (emphasis added). The Complaint alleges that Regeneron's payments were reportable price concessions on the facts alleged—and that Regeneron knew that was the case.

Because Regeneron cannot avoid that the Complaint contains extensive detailed allegations of Regeneron's knowledge, it instead suggests alternative explanations for those facts or protests that the Complaint could have contained even more allegations. But the narrow question for the Court is whether, taking the Complaint's allegations as true and drawing all inferences in the United States' favor, the Complaint plausibly alleges that Regeneron acted knowingly. At this stage, pursuant to Rule 9(b), the government is only required to plausibly and generally plead scienter under Rule 8. This it has done.

II. THE COMPLAINT AND THE CONSOLIDATED COMPLAINT SUFFICIENTLY ALLEGE UNJUST ENRICHMENT

Unjust enrichment requires "(1) a benefit conferred upon the defendant by the plaintiff; (2) an appreciation or knowledge by the defendant of the benefit; and (3) acceptance or retention by the defendant of the benefit under the circumstances would be inequitable without payment for its value." *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 552 F.3d 47, 57 (1st Cir. 2009). Here, the government has stated a claim for unjust enrichment by alleging that Regeneron knowingly inflated payment rates for Eylea and undermined the pricing regime for Eylea (and competing drugs). Compl. ¶ 121. As the Complaint alleges, Regeneron's conduct created financial incentives for customers to purchase and use Eylea, which Medicare and Medicaid paid for at rates directly tied to Eylea's inflated ASP. Doing so unjustly enriched Regeneron at the expense of the government and taxpayers by undermining market forces that would have lowered costs and payment amounts for Eylea.

Courts in the First Circuit, including in the cases cited by Regeneron, routinely deny motions to dismiss unjust enrichment claims, and permit pleading claims of unjust enrichment and violations of the FCA in the alternative. *See S. Bay Mental Health Ctr.*, 334 F. Supp. 3d at 405 (denying defendants' motion to dismiss unjust enrichment claim and holding that unjust enrichment could be pleaded as an alternative theory of liability); *Mylan Lab'ys*, 357 F. Supp. 2d 314, 323-24 (D. Mass. 2005) (rejecting defendant's argument that unjust enrichment count should be dismissed because an adequate remedy at law existed under the Massachusetts FCA, and holding that the court would "not force Plaintiff to choose its remedy at this stage of the litigation"); *see also United States ex rel. Kester v. Novartis Pharms. Corp.*, No. 11-CV-8196(CM), 2014 WL 4401275, at *11-12 (S.D.N.Y. Sep. 4, 2014); *In re Skat Tax Refund Scheme Litig.*, 356 F. Supp. 3d 300, 325 (S.D.N.Y. Jan. 9, 2019) ("The unjust enrichment claim alleges an alternative basis for relief from the fraud and negligent misrepresentation claims because both *scienter* and the defendants' liability for the alleged misrepresentations are disputed.") (emphasis in original). Because the government's allegations in support of its FCA claims also support a remedy based on unjust enrichment, Fed. R. Civ. P. 8(d)(3) permits the government to proceed on both causes of action, and the Court should deny Regeneron's Motion.

III. THE MOTION TO DISMISS THE CONSOLIDATED COMPLAINT SHOULD BE DENIED

Regeneron argues that the Consolidated Complaint should be dismissed for the same reasons as the Complaint. Mem. at 38. Regeneron identifies no additional reasons why the Consolidated Complaint should be dismissed. The intervening States join the United States in all arguments asserted herein against Defendant. Thus, for the reasons herein, Defendant's motion should be denied as to the Consolidated Complaint.

Regeneron makes two notable incorrect arguments with respect to the allegations in the

Consolidated Complaint. First, it is well-established that declination decisions do not support an inference on the merits of a case—and the fact that certain states declined to intervene does not support Regeneron's speculation, Mem. at 31, that alleged fraudulent conduct benefitted any government program. *See, e.g.*, *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006); *United States ex rel. Chandler v. Cook County, Ill.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd* 538 U.S. 119 (2003).

Second, Regeneron misconstrues the plain language of the Texas statute and moves to dismiss a conspiracy claim that Washington did not plead.[7] Concerning the Texas causes of action, the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ch. 36 ("TMFPA") (the Texas Health Care Program Fraud Prevention Act, as of September 1, 2023) is not identical to the FCA. *See In re Xerox Corp.*, 555 S.W.3d 518, 535 (Tex. 2018) (explaining that although the FCA and TMFPA are similar in aim and tactic, they "employ materially different language, and the language of [Texas's] statutes control the outcome here"). Regeneron acknowledges the notable distinctions between the TMFPA and the FCA but erroneously concludes that "Texas's claims thus rise and fall with the United States'." Mem. at 39. Unlike the FCA, however, the TMFPA sets out thirteen unlawful acts that each proscribe specific conduct generally involving misrepresentations made to the Medicaid program; none of the unlawful acts pled here require presentment of a false claim to incur liability. Tex. Hum. Res. Code §§ 36.002(1), (2) & (4)(B).

Federal courts recognize that the "interpretation of the TMFPA . . . is guided by Texas law." *United States ex rel. Bawduniak v. Biogen Idec Inc.*, No. 1:12-CV-10601-IT, 2022 WL 2438971, at *4 (D. Mass. July 5, 2022). The Texas Supreme Court has held that to interpret

[7] Regeneron misinterprets Count XII of the Consolidated Complaint, which characterizes certain conduct but which does not allege a conspiracy charge. Consol. Compl. ¶¶ 191-192.

statutes, "[o]ur standard is to construe the statutes to effectuate the intent of the Legislature, with the language of the statute as it was enacted to be our guide unless the context or an absurd result requires another construction." *City of Rockwall v. Hughes*, 246 S.W.3d 621, 629 (Tex. 2008). Consequently, Texas's claims against Regeneron must be analyzed according to the TMFPA's plain language, especially where the language differs from the FCA. *See United States ex rel. Govindarajan v. Dental Health Progs., Inc.*, No. 3:18-cv-00463-E, 2020 WL 3064712, at *7 (N.D. Tex. June 8, 2020). Federal courts have repeatedly determined that "[t]he TMFPA's scope can be broader than the FCA's scope." *See, e.g.*, *United States v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 607 (S.D. Tex. 2018), aff'd sub nom. *United States ex rel. Patel v. Catholic Health Initiatives*, 792 Fed. Appx. 296 (5th Cir. 2019). The Consolidated Complaint adequately pleads violations of the TMFPA independent of the United States' FCA claims.

CONCLUSION

For the foregoing reasons, Regeneron's Motion should be denied.

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Respectfully submitted,

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